TECHNICAL REPORT

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Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

Dispositifs médicaux — Lignes directrices pour le choix des normes correspondant aux principes essentiels reconnus de sécurité et de performance des dispositifs médicaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 16142 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO/TR 16142:1999), which has been technically revised.

Introduction

Standards and standardization processes can be made more effective by developing a better understanding of the needs and requirements of those who use or who are affected by standards. Improvements in standards will contribute to global harmonization efforts at all levels.

Continuous innovation is key to the advancement of medical device technology, contributing to more effective healthcare. Standards supporting or referenced in regulatory requirements need to be developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

Timely development and periodic revision make medical devices standards effective and efficient tools for supporting regulatory systems and for moving toward globally compatible regulation.

Voluntary standards and guides can assist manufacturers to comply with legal requirements. If the standards are accepted within a given regulatory system, compliance with such standards may be deemed to satisfy the legal requirements. The regulatory acceptance does not, of itself, imply that such standards are mandatory.

Medical device standards represent a consensus on requirements that foster innovation while protecting public health.

Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, can be facilitated by the appropriate use of relevant medical device standards.

This should be based on the premise that:

— standards are based on experience or, in other words, are retrospective;

— innovation may present unanticipated challenges to experience;

— rigid, mandatory, application of standards may deter innovation;

— operation of a quality management system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health;

— quality management systems include provisions that address both innovation and experience;

— such provisions of quality management systems include field experience, risk analysis and management, phased reviews, documentation and record keeping, as well as the use of product and process standards.

Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

1 Scope

This Technical Report considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

This Technical Report is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
basic standard
standard which includes fundamental concepts, principles, and requirements with regard to general aspects applicable to a wide range of products, processes, or services

NOTE Basic standards are sometimes referred to as horizontal standards.

2.2
group standard
standard which includes safety and essential performance aspects applicable to several or a family of similar products, processes, or services dealt with by two or more technical committees or subcommittees, making reference, as far as possible, to basic standards

NOTE Group standards are sometimes referred to as semihorizontal standards.

2.3
product standard
standard which includes all necessary safety and essential performance aspects of a specific or a family of product(s), process(es), or service(s) within the scope of a single technical committee or subcommittee, making reference, as far as possible, to basic standards and group standards

NOTE Product standards are sometimes referred to as vertical standards.

3 Essential principles of safety and performance of medical devices

Essential principles of safety and performance (after this, called “essential principles”) provide general requirements for design and production of all medical devices, ensuring their safety and performance. The concept of essential principles was developed by the Global Harmonization Task Force (GHTF; see Annex D). The concept is intended to encourage convergence in the evolution of regulatory systems for medical devices.

To ensure that, where relevant, the essential principles are met, a manufacturer may use consensus standards addressing the essential principles. Such standards provide a greater level of detail than can be expressed in the essential principles. Equally, legislators may find the essential principles and their related standards useful in the context of regulatory systems for medical devices.

4 Use of standards and guides in support of regulatory requirements

4.1 Basic standards

Basic standards are developed to address the essential principles that are applicable to all kinds or a wide range of medical devices. Basic standards provide the technical details needed to satisfy compliance with the essential principles. The development and use of basic standards is encouraged as this minimizes the proliferation of standards and prevents the development of divergent or conflicting requirements or expectations. Basic standards support the development of consistent expectations between regulatory authorities and manufacturers. In general, member bodies should adopt international consensus standards without alteration.

Basic standards can be broadly categorized into:

— management systems standards, e.g. quality management systems, risk management, and

— essential safety standards or standards specifying requirements for a process, e.g. biological safety, general requirements for safety and essential performance for medical electrical equipment, sterilization, and usability.

4.2 Recognition of standards

In some countries, regulatory authorities recognize the use of voluntary consensus standards as one means of demonstrating compliance with relevant essential principles of safety and performance of medical devices. When a recognized consensus standard is either

a) not utilized,

b) not available, or

c) not applied in full,

this is acceptable if an equivalent level of compliance with the essential principles of safety and performance can be achieved and demonstrated through other means. In the absence of international consensus standards, it may be appropriate for regulatory authorities to accept the use of regional or national consensus standards or industry standards.

Standards suitable to address the essential principles should be based on:

— a close relationship of the scope of the standard to one or more of the essential principles,

— the clarity and completeness of the technical requirements contained in the standard,

— the existence of methods for determining compliance with each of the technical requirements in the standard,

— the definition of clear criteria for determining that the technical requirements are met.

4.3 Conformity assessment

In assessing the conformity of a medical device with the essential principles, a manufacturer of a particular medical device may utilize parts of several standards and combine them in a way that is considered to be appropriate for the device in question. The use of parts and/or combinations of standards should be acceptable for conformity assessment purposes.

Specific product standards are necessary where basic and/or group standards do not cover all the necessary essential principles of safety and performance.

4.4 Reference to basic standards

It can be appropriate for a standard to make a reference to a basic standard in order to ensure consistent application of requirements. Such references should be made with caution so as not to limit any options allowed by regulatory requirements and conformity assessment procedures, especially in the situations in which product standards need to make normative reference to basic standards for management systems (see 4.1). There is general agreement that controlling certain processes is the best way, or the only way, of ensuring that the products emerging from the processes meet regulatory requirements. Classic instances are for sterile products and for software; therefore standards for sterile products and products utilizing software are examples where it can be appropriate to call up basic standards. However, caution is appropriate before requiring application of Management System Standards through normative reference in a product standard.

Manufacturers using standards to support conformity with regulatory requirements have the option of using all or part of a standard (see 4.3).

Basic standards may be evoked by other standards in a number of ways. Examples are:

— specifying requirements for systems or properties supported by informative reference to a basic standard,

— including normative reference to identified requirements, clauses or subclauses of a basic standard,

— specifying requirements using verbatim text taken from a basic standard and citing the source document informatively, or

— including normative reference to a basic standard.

Examples of these approaches are given in Annex B.

It can also be appropriate to make normative reference from one product standard to another, following the above guidelines.

5 Essential principles and references to relevant standards or guides

Before placing a medical device on the market, a manufacturer has to establish that the applicable essential principles of safety and performance have been met in a satisfactory way.

There may be a number of ways for a manufacturer to demonstrate compliance to essential principles.

In Annex A, a number of significant standards are indicated which may be suitable for demonstrating compliance with certain features of the related essential principles as listed in Table A.1.

When selecting standards from Annex A, it is important to consider the type of the device and process concerned, as some standards listed relate to particular families of devices, or processes (e.g., IEC 60601 relates to medical electrical equipment).

It is recognized that the requirements in a single standard may not meet all the features of a given essential principle as related to a given device. Other standards may be available, or under development, that can assist in demonstrating that a device meets all the relevant essential principles.

The standards referenced in Annex A may be used as a starting point, and any reference material intended to be used should be checked against a maintained source for the latest effective revision.

It is not possible in this Technical Report to identify all standards that may be used to meet particular essential principles.

6 How to find relevant standards

The following Internet addresses are available to aid in locating standards:

— ISO http://www.iso.org

— IEC http://www.iec.ch

National member bodies of ISO and IEC may have national standards equivalent to those listed in Annex A, although the numbers may not be the same.

Annex A
(informative)

Table relating essential principles to standards

The list of standards in Table A.1 is to be used as a starting point. Any reference material intended to be used should be checked against a maintained source for the latest effective revision.

Standards that are referenced for a major category of essential principles are potentially applicable to most if not all of the specific principle in the category. Where standards are limited to one or a few specific principles, references are made specific to the associated principle.

Other types of documents may be useful, in particular for standards writers.

Some of these documents are:

— ISO Guide 51, *Safety aspects — Guidelines for their inclusion in standards*

— ISO Guide 63, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*

— IEC 60513, *Fundamental aspects of safety standards for medical electrical equipment*

In this annex, a number of significant standards are indicated which may be suitable for demonstrating compliance with certain features of the related essential principles. Other standards may be available, or under development, that can assist in demonstrating that a device meets all the relevant essential principles.